Exhibit D

From: n kamberland <kamberland@hotmail.com>
Sent: Saturday, August 23, 2014 5:59 PM
To: Klontz, Karl C <Karl.Klontz@fda.hhs.gov>
Subject: RE: OEP paper - please review

Hi Karl,
Thanks for the clarification/explanation!

Pam

From: Karl.Klontz@fda.hhs.gov
To: kamberland@hotmail.com
Subject: RE: OEP paper - please review
Date: Sat, 23 Aug 2014 19:55:23 +0000

Pam,

I wanted to respond to a couple of your thoughtful suggestions and comments…

First, you stated the following about statements in the Discussion below, "Not sure this is accurate. I thought all the cases that were identified consumed OEP with aegeline in it."

Manuscript: *It is possible that DMAA also contributed to liver injury during the study period in consumers who ingested OxyELITEPro™ containing this ingredient. Given that it was not until April of 2013 that USPlabs LLC announced its intention to phase out products containing DMAA, it is likely that DMAA-containing product may have been available for purchase through the study period at least until the first half of 2013.*

Keep in mind, FDA did not sample/analyze ALL of the product that ill persons consumed. Because of this, we really do not know that illness was confined exclusively to product containing aegeline. Moreover, as we state in the manuscript, DMAA-containing product was most likely available through the first half of 2013. Because FDA received reports of liver injury in persons who had ingested OxyElitePro prior to the addition of aegeline (albeit infrequently), we believe it's at least possible that some cases during the study period could have been due to DMAA.

With regard to the laboratory analysis section, you stated, "This is a bit confusing making it seem that the outbreak could have been linked to DMAA. I do not believe this is the case." Accordingly, I altered the text to read: "*Non-targeted liquid chromatography / gas chromatography demonstrated the presence of combinations of aegeline, higenamine, caffeine, and yohimbine, or, in some products, a trio of DMAA, caffeine, and yohimbine*." You also stated, "It may be helpful to indicate that no adverse lab results were seen." That's the purpose of the following narrative we included: "*The following agents were absent: drugs, poisons, pharmaceuticals, toxic metals, usnic acid, N-Nitroso-fenfluoramine, pyrrolizidime alkaloids, aristocholic acid, and phenethylamines.*"
Finally, I didn't make mention of the mandatory recall authority FDA had because that would raise the need for

explain what that authority is and to provide further background and context regarding the authority. Thus, for the sake of brevity, I decided to omit reference to it.
I've attached a copy of the paper that reflects the change cited above in the laboratory analysis section.
Let me know if you have any additional comments or suggestions. We plan to seek CORE clearance this upcoming week. (CFSAN clearance is already underway.)
Karl

From: n kamberland [mailto:kamberland@hotmail.com]
Sent: Friday, August 22, 2014 2:12 PM
To: Klontz, Karl C
Cc: Salter, Monique; Seelman, Sharon
Subject: RE: OEP paper - please review

Hi Karl,
The paper looks great!

Attached are a few suggested edits for consideration.

Thanks,
Pam

From: Karl.Klontz@fda.hhs.gov
To: kamberland@hotmail.com
Subject: OEP paper - please review
Date: Mon, 18 Aug 2014 14:56:57 +0000
Hi Pam,

Please find attached the latest version of the OEP paper. May I ask you to review it one more time and provide any comments or changes you feel strong about by August 25th? I plan to submit it for CFSAN clearance shortly after that date.

The graphics folks are touching up the figures so please forgive the somewhat fuzziness of the draft figures provided here. The professional ones are much sharper.

I'll work with Monique and others in CORE to request clearance through OFVM as I work on CFSAN clearance. I will also seek assistance in getting CVM clearance.

Many thanks.

Karl